Statistical Analysis Plan (SAP) & Open Science Framework (OSP)

Study Information

Title

Evaluating the Effectiveness of the Breastfeeding Support Program in Promoting and Sustaining Breastfeeding at 6-8 Weeks Postpartum: A Quasi-Experimental Study

Authors

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Description (optional)

Hypotheses

Primary Outcome:

Participation in the Breastfeeding Support (BFS) intervention will increase the likelihood of any breastfeeding at 6–8 weeks postpartum compared to receiving standard care in the BSB area.

Secondary Outcomes:

1. The BFS intervention will lead to higher exclusive breastfeeding rates at 6–8 weeks postpartum.
2. The BFS intervention will lead to higher rates of any breastfeeding at 6 months postpartum.
3. The mode of delivery (in-person vs. telephone/virtual) of BFS support will influence breastfeeding outcomes.
4. The number of BFS support contacts will be positively associated with any breastfeeding at 6–8 weeks postpartum.
5. Interpreter use during BFS support will be associated with differences in breastfeeding rates at 6–8 weeks postpartum.
6. Exclusive and any breastfeeding rates will differ between mothers who received in-person BFS support pre-pandemic and those who received virtual/telephone support during the pandemic.

The effectiveness of the BFS intervention on breastfeeding at 6–8 weeks postpartum will vary by: Language; and Presence of maternal depression during pregnancy

Design Plan

Study type

Observational Study - Data is collected from study subjects that are not randomly assigned to a treatment. This includes surveys, natural experiments, and regression discontinuity designs.

Study design

This study is a quasi-experimental evaluation designed to assess the effectiveness of the Breastfeeding Support intervention in promoting and sustaining breastfeeding among women in the Better Start Bradford area.

Blinding

Due to the nature of the intervention, blinding of participants and intervention providers is not feasible.

Sampling Plan

Existing Data

This study will use existing data from the Born in Bradford's Better Start (BiBBS) cohort. As of the submission date, no one has quantified, constructed, observed or reported these data, including those not involved in the proposed study. This ensures the data is clean and unbiased.

Explanation of Existing Data

Born in Bradford's Better Start (BiBBS) is an interventional family cohort study to evaluate the effectiveness of early life interventions delivered by Better Start Bradford. BiBBS is part of the Born in Bradford (BiB) family of studies. The cohort has comprehensive baseline data collected during pregnancy and consent for routine linkage to health and education records and intervention participation information. BiBBS also administers a postnatal questionnaire to mothers 6-10 weeks after birth which is the primary and secondary outcome for this study. The cohort data also shows high proportions of pregnant women reporting symptoms of depression and anxiety which will be useful for evaluating the impact of the intervention.

Data Collection Procedures

Data for this study will be collected from three primary sources:

Data Source	**Description**	**Key Variables**
BiBBS Baseline Questionnaire	Completed by women recruited into the BiBBS cohort from 1st Nov 2018 to March 2024. Includes extensive demographic and psychosocial data. Used for propensity score matching and subgroup analyses.	- Demographics- Mental health- Socioeconomic status- Family background
Breastfeeding Support Project Data	Collected by the service for all participants referred to or engaged with the BFS intervention. Data includes referral, contact, and support delivery details. Linked via NHS number.	- Referral status- Contact made- Enrollment- Support contact dates- Format of contact- Discharge

Health Visiting Data	Feeding outcomes collected during routine health visit at 6–8 weeks postpartum, from health records (SystmOne).	- Feeding status at 6–8 weeks - Feeding status at 6 months

Sample Size

Sample size calculations for the primary objective were conducted using Stata 18 to estimate required sample sizes for detecting differences in proportions between two groups. The analysis focused on the effectiveness of the Breastfeeding Support intervention in improving the probability of any breastfeeding at 6-8 weeks postpartum.

Assumptions:

- Baseline breastfeeding rate of 55% at 6 weeks (based on local data)
- Two-tailed alpha = 0.05
- Power = 80%
- Risk difference (effect size): 8%
- Equal and unequal group allocation scenarios

Sample Size Estimates:

- For equal group sizes (1:1 allocation): A total of 1,186 participants (593 per group) are required to detect an 8% difference in breastfeeding rates with 80% power.
- For unequal group sizes (1:2 allocation): A total of 1,329 participants (443 in the intervention group and 886 in the comparison group) are required to detect the same 8% difference with 80% power.

Participants

The participants in this study are mothers of infants, with data collected at both the mother and child levels.

Intervention Group: Women who participated in the Breastfeeding Support service, with at least one support contact, and completed the BiBBS baseline questionnaire.

Control Group: Women who delivered during the Breastfeeding Support intervention delivery period but did not participate in the intervention and completed the BiBBS baseline questionnaire.

Eligibility Criteria:

Intervention Group:

- Participated in the Breastfeeding Support service.
- Completed the BiBBS baseline questionnaire.
- Neither mother nor infant was admitted to ICU/NICU following delivery.
- No documented medical reason for refusal (e.g., maternal or infant health complications, contraindicated medications).
- Breastfeeding support was offered within 6-8 weeks postpartum.

Control Group:

- Delivered during the Breastfeeding Support intervention delivery period.
- Did not participate in the Breastfeeding Support intervention.
- Completed the BiBBS baseline questionnaire.
- Neither mother nor infant was admitted to ICU/NICU following delivery.
- No documented medical reason for refusal (e.g., maternal or infant health complications, contraindicated medications).
- Did not receive a late offer of breastfeeding support (i.e., no offer made after 6-8 weeks postpartum).

Variables

All individuals who enrolled in the Breastfeeding support program are classified as participants in the 'treatment group.' A corresponding control group will be established using propensity score matching based on selected matching variables. Detailed information about the questionnaires used and the rationale for choosing these variables can be found in the study protocol. The table below outlines how each variable will be measured and coded.

Table 2. Description of outcome variables

Variable Type	Variable	Source	Measurement type	Range	Codes
Exposure	Breastfeeding Support Intervention	Breastfeeding Support Project Data	Binary	N/A	[0 No] [1 Yes]

Variable Type	Variable	Source	Measurement type	Range	Codes
Primary Outcome	Any Breastfeeding at 6–8 Weeks	Health Visiting Data (Routine Records)	Binary/Categorical (Any / None)	N/A	[0 No] [1 Yes]
Secondary Outcome	Exclusive Breastfeeding at 6–8 Weeks	Health Visiting Data (Routine Records)	Binary/Categorical (Exclusive / Not)	N/A	[0 No] [1 Yes]
Secondary Outcome	Any breastfeeding at 6 Months	Health Visiting Data (Routine Records)	Binary/Categorical (Exclusive / Not)	N/A	[0 No] [1 Yes]

Moreover, by analysing the data from before, during, and after the COVID-19 pandemic, we will evaluate the impact of the pandemic on the changes in intervention implementation and the effectiveness of the intervention. The number of contacts each participant received and the format in which the intervention was delivered (face-to-face vs. telephone) will be recorded and examined to assess their impact on the effectiveness of the intervention. We will also assess if there is any difference in effectiveness of the intervention among participants whose first language is English and those for whom English is a second language.

Matching variables

Table 2. Covariates for matching obtained from BiBBS baseline questionnaire

Matching variables	**Source**	**Measurement Type**	**Range**	**Code**
Primary Language	BiBBS baseline data	Categorical	N/A	Categorical (English as first language / English as second language)
Maternal Age	BiBBS baseline data	Continuous	16+	N/A
Socioeconomic position	BiBBS baseline data	Categorical	N/A	[0 Living comfortably, 1 Doing alright, 2 Just about getting by, 3 Finding it quite/very difficult, do not wish to answer and don't know responses will be recoded as missing variables]
Relationship Status	BiBBS baseline data	Categorical	N/A	[1 Married] [2 In relationship but not married] [3 Separated or divorced] [4 Never been in a relationship with] [5 Has died]
Parity (First Child or Not)	Primary care data	Binary	N/A	[0 Not first pregnancy, 1 First pregnancy]
Ethnicity	BiBBS baseline data	Categorical	N/A	[0 White, 1 Asian, 2 other]
Smoking Status	BiBBS baseline data	Categorical	N/A	[0 No] [1 Yes]

Breastfeeding Intention	BiBBS baseline data	Binary / Categorical	N/A	[0 No] [1 Yes]

Economic outcomes

A health economic analysis will be conducted consisting of three elements:

1) Investigation of the costs associated with delivering the Breastfeeding support programme, including staff time, training, and deliverables. This will make use of financial returns available from the BSB finance team. Where possible we will seek to distinguish between sunk setup costs of the programme from ongoing variable costs.

2) A pragmatic literature review of the previously estimated long term health impact of increasing uptake and continuation of breastfeeding on the mother and child. This will explore existing evidence on the long term costs and benefits of breastfeeding with a focus on a healthcare perspective. The review will utilise online journal databases (e.g. Cochrane Library and Medline) to conduct a key work search which will be supplemented via reference and citation searching of relevant studies. An exploration of the grey literature will also include leveraging known policy resources (e.g. National Institute for Health and Care Excellence (NICE) Guidance, World Health Organisation) and online search engines.

3) A threshold analysis considering the scale of additional benefits that would need to be achieved for an intervention like that delivered through the BSB programme to be considered cost saving or cost-effective under conventional analytical perspectives such as the NICE Reference Case. This analysis will utilise the findings of the previous two elements in addition to wider evidence on the cost and impact of diseases that have been purported to be affected by breastfeeding such as obesity rates.

Analysis Plan

Descriptive Analysis

Descriptive statistics will be used to summarise the baseline characteristics of the study population, both overall and stratified by intervention and control groups (post-matching). This will allow for a clear understanding of the sample composition. Maternal age and BMI along with other continuous variables will receive summary statistics that use the mean and standard deviation for normal distributions while using median and interquartile range for skewed distributions. Visual inspection through histograms and Q-Q plots along with formal Shapiro-Wilk tests will evaluate distribution properties.

Step 1: Propensity Score Matching

A matched control group for the intervention group will be generated using the propensity score matching method. The propensity score represents the likelihood of a subject receiving the treatment, given a set of covariates (Benedetto et al., 2018). We will employ one-to-many matching with the propensity score method to enhance statistical power (Barth et al., 2008). After specifying the propensity score, a critical aspect of any propensity score analysis is evaluating whether the model has been appropriately specified.

- Objective: To create comparable groups of participants who received the Breastfeeding Support intervention and those who did not, thereby controlling for potential confounding variables.
- Method: Propensity scores will be estimated using logistic regression, where the probability of receiving the intervention is modelled based on baseline covariates (e.g., maternal age, language, socioeconomic status, breastfeeding intention).
- Matching Algorithm: Kernel matching will be employed to enhance statistical power and ensure a good balance between the intervention and control groups.
- Assessment of Matching Quality: Standardized mean differences (SMDs) will be calculated for each covariate to assess the balance between groups. An SMD of less than 0.2 will be considered indicative of adequate balance.

Step 2: Impute Outcome Data

Multiple imputation will be performed using chained equations (MICE), with the number of imputations set based on the percentage of missing data (e.g., 20 imputations if up to 20% missing). If the proportion of missing data is ≤5%, imputation will not be conducted, as such a low level of missingness is generally considered ignorable (Dong & Peng 2013; Bennett, 2001). Only outcome variables will be imputed; participants with missing baseline covariates or exposure data (i.e., variables used in the propensity score model) will be excluded from the analysis. To preserve associations, the imputation model will include all covariates, the exposure variable (intervention group), and the outcome variables. After imputation, PS matching will be conducted separately within each dataset using the same kernel matching

approach. The matched datasets will be analysed using logistic regression models, and treatment effects will be combined across imputations using Rubin's rules.

Missingness in routine health data may not fully meet the assumptions of Missing at Random (MAR); however, we assume that missing outcome data (e.g., breastfeeding status at 6–8 weeks) can be at least partially explained by observed baseline characteristics (e.g., maternal age, language, SES, breastfeeding intention). These are also the same variables used for propensity score estimation.

Approaches to combining MI and PS methods:

In the literature, two approaches to integrating MI and PS estimation are commonly used:

- MI first, then estimate PS: Impute covariates and outcomes first, then estimate PS in each imputed dataset, perform causal analyses, and pool results.
- Estimate PS first, then MI: Estimate PS in each imputed dataset separately, apply causal methods, and pool treatment effects.

We will adopt Approach 1 (MI first, then PS). This method ensures that PS estimation reflects uncertainty in imputed baseline characteristics and avoids the risk of conditioning on post-treatment variables or inadvertently excluding participants due to incomplete covariates (Nguyen et al. 2024; Granger, et al. 2019). A complete-case analysis will be conducted to compare results from imputed datasets.

A sensitivity analysis using complete cases (i.e., those participants with no missing outcome data) will be conducted alongside the imputed datasets. The goal of this sensitivity analysis is to compare the treatment effect estimates derived from the imputed datasets with those from complete cases. This will help assess whether the imputation approach affects the interpretation of the intervention's effectiveness.

Step 3: Regression Analyses

After matched groups have been created and outcomes have been imputed, binary logistic regression analyses will be conducted using group assignment (intervention vs. control) as the independent variable and breastfeeding status (any breastfeeding, exclusive breastfeeding) as the dependent variable. In addition to group assignment, various covariates will be included in the models. Results will be reported as odds ratios (ORs) with 95% confidence intervals (CIs).

Additional regression analyses will be conducted to evaluate factors associated with the rate of exclusive breastfeeding at 6–8 weeks postpartum among mothers in the intervention group. A multivariable logistic regression model will be used to assess associations between exclusive breastfeeding and the following explanatory variables: Intervention dose (e.g., number of contacts or sessions received), Format of delivery (e.g., in-person, telephone, or mixed-mode support), Use of interpreters (yes/no), COVID-19 period effects (e.g.,

pre-pandemic vs. pandemic/post-pandemic phases). These variables will be entered into the model simultaneously, and adjustments will be made for potential confounders, such as maternal age, ethnicity, parity, BMI, and language background. Model diagnostics will be performed to assess fit and multicollinearity, and results will be presented as adjusted odds ratios (aORs) with 95% confidence intervals. If missing data are present in key covariates, multiple imputation will be considered, assuming data are missing at random (MAR).

References

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